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DEFINING THE RIGHT TO HEALTH RESPONSIBILITIES OF PATENT-OWNING PHARMACEUTICAL COMPANIES

SUMMARY

The overlap in the mandates of the former Special Rapporteur on the right to health (Paul Hunt) and the Special Representative of the Secretary-General on business and human rights (John Ruggie) has resulted in some inconsistencies between the Guidelines developed by Hunt and the Guiding Principles developed by Ruggie concerning defining the precise scope of the right to health responsibilities of pharmaceutical companies. Nevertheless, defining the right to health responsibilities of pharmaceutical companies is possible through an interpretation of the Hunt Guidelines in the light of the Guiding Principles. This article focuses on defining the right to health responsibilities of patent-owning pharmaceutical companies. It contends that, for this definition of responsibilities to be meaningful, states must take seriously their primary responsibility of respecting, protecting, and fulfilling the right to health by incorporating a model of human rights into their national patent laws. Furthermore, pharmaceutical companies must take seriously their baseline responsibility of respecting the right to health and complying with the provisions contained in national patent laws that are designed to facilitate access to affordable medicines.

INTRODUCTION

The exorbitant prices charged by some producers of patented pharmaceutical products has drawn the ire of governments and patients in both developed and developing countries.¹ Patented drugs, which are life-saving but expensive, typically remain inaccessible to poor patients and this has an impact on their human right to health. It is therefore crucial to clarify whether patent-owning pharmaceutical companies have any responsibilities in relation to the right to health.

Following the endorsement of the ‘Guiding Principles on Business and Human Rights’² prepared by John Ruggie (hereinafter, Guiding Principles) by the United Nations Human Rights Council in June 2011, it has become widely acknowledged that business enterprises have a responsibility to respect human rights. In addition, in 2008, Paul Hunt (the United

¹ United Nations Secretary-General’s High-Level Panel on Access to Medicines, ‘Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies,’ (September 2016) 12, <http://www.unsgaccessmeds.org/final-report/> (accessed 12 March 2017), (noting that, ‘the High-Level Panel views access to medicine, vaccines, diagnostics and related health technologies as a serious, multi-dimensional global problem, with challenges that affect all people and all countries ... the High-Level Panel recognizes that the costs of health technologies are rising globally and are being felt by individuals and by public and private insurance schemes in both wealthy and resource-constrained countries alike. These rising costs have the potential to push more people into poverty.’). See also, Sarah Boseley, ‘Why Do New Medicines Cost So Much, and What Can We Do about It?’ *The Guardian*, (9 April 2018), <https://www.theguardian.com/news/2018/apr/09/why-do-new-medicines-cost-so-much-and-what-can-we-do-about-it> (accessed 15 April 2018), (noting that, ‘The cost of new drugs is putting increasing pressure on people in both rich and poor countries.’).

² Human Rights Council, ‘Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework,’ U.N. Doc. A/HRC/17/31, (21 March 2011).

Nations Special Rapporteur on the right to health between 2002 and 2008) presented his report containing the ‘Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines’³ (hereinafter, Hunt Guidelines) to the United Nations General Assembly. Thus, considerable work has been done to enunciate the right to health responsibilities of pharmaceutical companies.⁴

However, the overlap between the mandates of Ruggie and Hunt has led to some inconsistencies with regard to the identification of the right to health responsibilities of pharmaceutical companies. Importantly, while the Guiding Principles emphasize the baseline responsibility of corporate actors to respect human rights, the Hunt Guidelines go beyond this baseline responsibility to respect human rights. It has therefore become necessary to further clarify the precise scope of the right to health responsibilities of pharmaceutical companies. In this regard, a notable attempt has been made by Suerie Moon to analyse the Hunt Guidelines in the light of the Guiding Principles.⁵ There are however some gaps in Moon’s analysis and this article seeks to build on Moon’s analysis and provide further clarifications on the scope and content of the right to health responsibilities of patent-owning pharmaceutical companies.

This article contends that, for the definition of the responsibilities of pharmaceutical companies to be meaningful, states must take seriously their primary responsibility of respecting, protecting, and fulfilling the right to health by incorporating a model of human

³ Paul Hunt, ‘Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines,’ U.N. Doc. A/63/263, (11 August 2008).

⁴ Joo-Young Lee and Paul Hunt, ‘Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines’ (2012) 40 *The Journal of Law, Medicine & Ethics* 220.

⁵ Suerie Moon, ‘Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry’ (2013) 15 *Health and Human Rights* 32.

rights into their national patent laws. In addition, pharmaceutical companies must take seriously their baseline responsibility of respecting the right to health and complying with the provisions contained in national patent laws that are designed to facilitate access to affordable medicines. This article is divided into three main parts. Part one of this article will discuss the status of health as a human right under international law. Part two will provide some background to both the Guiding Principles and the Hunt Guidelines. Part three of the article will be devoted to clarifying the scope of the right to health responsibilities of patent-owning pharmaceutical companies especially as it relates to facilitating access to affordable medicines in the light of both the Hunt Guidelines and the Guiding Principles.

1. HEALTH AS A HUMAN RIGHT

The human right to health⁶ is recognized in several international legal instruments and in the constitutions of a number of countries across the world.⁷ The recognition of this right in legal

⁶ The discussion on the right to health in this article focuses mainly on highlighting the right-to-health obligations of both state and non-state actors as contained in the International Covenant on Economic, Social and Cultural Rights and as elaborated upon by the UN Committee on Economic, Social and Cultural Rights in its General Comment No. 14. See, UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 14, The Right to the Highest Attainable Standard of Health (Article 12)' E/C.12/2000/4 (2000). Hence, this article does not discuss the historical development of the right to health. For a discussion of the historical development of the right to health, see, John Tobin, *The Right to Health in International Law* (Oxford: Oxford University Press, 2012) 14-43. In addition, while recognizing the debate surrounding the conceptual foundations of the right to health, an exhaustive examination of the arguments in this debate is beyond the scope of this article. For arguments against the right to health in particular and economic and social rights in general, see: William Easterly, 'Human Rights Are the Wrong Basis for Healthcare' *The Financial Times* (12 October 2009), <https://www.ft.com/content/89bbdda2-b763-11de-9812-00144feab49a> (accessed 12 March 2017); James Griffin, *On Human Rights* (Oxford: Oxford University Press, 2008) 208-209; Aryeh Neier, 'Social and

instruments, however, is not a guarantee that it is being enjoyed on an equal basis universally. The enjoyment of this right is further curtailed by the present global structure for the protection of intellectual property rights, especially patent rights. Patent rights have a direct impact on the right to health, especially in developing countries where pharmaceutical products are priced beyond the reach of poor patients.

One of the international agreements that provides for the right to health is the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12(1) of the ICESCR mandates the states parties to the Covenant to ‘recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’. In 2000, the UN Committee on Economic, Social and Cultural Rights (CESCR) adopted General Comment

Economic Rights: A Critique’ (2006) 13 *Human Rights Brief* 1-3; Onora O’Neill, ‘The Dark Side of Human Rights’ (2005) 81 *International Affairs* 427; Maurice Cranston, ‘Are There Any Human Rights?’ (1983) 112 *Daedalus* 1. For arguments in support of the right to health, see: John Tobin, *ibid*, 44-74; Jonathan Wolff, *The Human Right to Health* (New York & London: W. W. Norton & Co., 2012) 13-38; Jennifer Ruger, ‘Towards a Theory of a Right to Health: Capability and Incompletely Theorized Agreements’ (2006) 18 *Yale Journal of Law and the Humanities* 273; Jennifer Ruger, *Health and Social Justice* (Oxford: Oxford University Press, 2010) 118.

⁷ The Constitution of the WHO, 1946; Article 25 of the Universal Declaration of Human Rights, G.A. Res. 217A (III) (1948); Article 12 of the International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI) (1966). See also, Section 27 of the South African Constitution, 1996; Article 43(1)(a) of the Kenyan Constitution, 2010; and Article 196 of the Brazilian Constitution, 1988. There is also judicial recognition of the right to health as an integral component of the constitutional right to life in India. See for instance, *Consumer Education & Research Centre & Ors. v Union of India & Ors.*, 1995 SCC (3) 42 (decided on 27 January 1995); *Paschim Banga Khet Samity v State of West Bengal*, (1996) 4 SCC 37 (decided on 6 May 1996); *State of Punjab v Ram Lubhaya Bagga*, (1998) 4 SCC 117 (decided on 26 February 1998); *Mohd. Ahmed (Minor) v Union of India and others*, W.P.(C) 7279/2013 (decision of the High Court of Delhi at New Delhi, 17 April 2014).

No. 14 in an attempt to provide further definition for Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁸ Paragraph 12 of General Comment No. 14 is very relevant to the question of access to medicines. It enumerates four essential, interrelated components of the right to health: availability, accessibility, acceptability, and quality. In particular, it provides that essential drugs (as defined by the World Health Organization Action Programme on Essential Drugs) must be available in a country.⁹

According to the World Health Organization (WHO), essential drugs are drugs that ‘satisfy the priority health care needs of the population’ and ‘are intended to be available within the context of functioning health systems at all times in adequate amounts ... and at a price the individual and the community can afford.’¹⁰ In addition, General Comment No. 14 states that health care services must be economically accessible to everyone, suggesting that the prices of essential drugs should not be so expensive as to be unaffordable for poor patients.¹¹ This makes access to essential medicines an integral component of the right to health.¹² Furthermore, states are obliged to take steps ‘to control the marketing of medical equipment and medicines by third parties’.¹³ It has been suggested that this implies that ‘states should

⁸ CESCR, ‘General Comment No. 14,’ note 6.

⁹ Ibid para 12(a).

¹⁰ World Health Organization, “Essential Medicines.” Available at http://www.who.int/topics/essential_medicines/en/ (accessed 12 March 2017).

¹¹ CESCR, ‘General Comment No. 14,’ note 6, para 12(b).

¹² Mirela Hristova, ‘Are Intellectual Property Rights Human Rights? Patent Protection and the Right to Health’ (2011) 93 *Journal of the Patent & Trademark Office Society* 339, 356. See also, Human Rights Council, ‘Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health,’ A/HRC/RES/23/14 (2013).

¹³ CESCR, ‘General Comment No. 14,’ note 6, para 35.

intervene where marketing of drugs by pharmaceutical companies is detrimental to the right to health'.¹⁴

States have an obligation to respect, protect and fulfil the right to health.¹⁵ The obligation to *respect* the right to health demands that states should not interfere directly or indirectly with the enjoyment of the right to health.¹⁶ Essentially, the obligation to respect the right to health requires that states should, *inter alia*, 'refrain from denying or limiting equal access for all persons ... to preventive, curative and palliative health services'.¹⁷ The obligation to *protect* the right to health requires states to, *inter alia*, 'adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties'.¹⁸ The obligation to *fulfil* the right to health demands that states should, *inter alia*, 'give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health'.¹⁹

It is contended here that the obligation of states to respect, protect and fulfil the right to health has implications for the design, implementation, interpretation and enforcement of their national patent laws. The obligation to fulfil the right to health demands that, when designing or amending their national patent laws, states should recognize the possible implications of

¹⁴ Stephen Marks, 'Access to Essential Medicines as a Component of the Right to Health' in A Clapham and M Robinson (eds), *Realizing The Right to Health*, Swiss Human Rights Book Series, vol 3 (Zurich: Ruffer & Rub, 2009) 90.

¹⁵ CESCR, 'General Comment No. 14,' note 6, para 33.

¹⁶ Ibid para 33.

¹⁷ Ibid para 34.

¹⁸ Ibid para 35.

¹⁹ Ibid para 36.

such legislative proposals for the enjoyment of the right to health.²⁰ In order to effectively protect the right to health, patent rights owned by third parties such as pharmaceutical companies should not be implemented and enforced in a manner that makes it more difficult for poorer citizens to have access to affordable generic drugs.²¹ Furthermore, the obligation to respect the right to health requires that when designing, implementing, or interpreting patent laws, the various arms and organs of government (including the courts) should not adopt an approach that impedes the enjoyment of the right to health.²² States equally have core obligations with regard to the right to health.²³ One of the core obligations of states is to ‘provide essential drugs, as from time to time defined under the WHO Action Programme on

²⁰ Ibid para 52 (stating that, ‘Violations of the obligation to fulfil occur through the failure of States parties to take all necessary steps to ensure the realization of the right to health.’)

²¹ Ibid para 51 (stating that, ‘Violations of the obligation to protect follow from the failure of a State to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties. This category includes such omissions as the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others’.).

²² Ibid para 50 (stating that, ‘Violations of the obligation to respect are those State actions, policies or laws that contravene the standards set out in article 12 of the Covenant and are likely to result in bodily harm, unnecessary morbidity and preventable mortality. Examples include ... the suspension of legislation or the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health; and the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations.’).

²³ Ibid para 43.

Essential Drugs'.²⁴ It must be stressed that a core obligation is one from which no derogation is permissible.²⁵

2. PHARMACEUTICAL COMPANIES AND THE RIGHT TO HEALTH

Business entities such as pharmaceutical corporations also have right to health obligations. As the CESCR points out in General Comment No. 14,

While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society - individuals, including health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations, as well as the private business sector - have responsibilities regarding the realization of the right to health.²⁶

The above statement indicates that the CESCR took the view that corporate actors (and other actors in the society) have responsibilities with regard to the right to health. However, the CESCR does not provide any elaboration on the specific nature of the responsibilities of corporate actors in relation to the right to health. Fortunately, this gap has now been filled by the Ruggie Guiding Principles and the Hunt Guidelines. However, before delving into both the Guiding Principles and the Hunt Guidelines, it is important to examine prior attempts that have been made at the global level to develop rules or norms to regulate the activities of

²⁴ Ibid para 43(d).

²⁵ Ibid para 47 (noting that, 'It should be stressed, however, that a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are non-derogable').

²⁶ Ibid para 42.

corporate actors. These prior attempts provide the historical backdrop and context for both the Guiding Principles and the Hunt Guidelines.

The first attempt at the adoption of rules to regulate the activities of corporate actors at the international level started in the 1970s with the negotiations on the United Nations Code of Conduct on Transnational Corporations (hereinafter, the Code).²⁷ The negotiations on the Code occurred under the auspices of the United Nations Centre on Transnational Corporations (UNCTC).²⁸ The immediate cause of the negotiations on the Code can be traced back to the interferences by corporate actors in the 1973 Chilean coup d'état.²⁹ In addition,

²⁷ See generally, Tagi Sagafi-nejad, *The UN and Transnational Corporations: From Code of Conduct to Global Compact*, (Indiana University Press, 2008); Karl Sauvant, 'The Negotiations of the United Nations Code of Conduct on Transnational Corporations: Experience and Lessons Learned,' (2015) 16 *The Journal of World Investment & Trade* 11.

²⁸ See, Khalil Hamdani and Lorraine Ruffing, *United Nations Centre on Transnational Corporations: Corporate Conduct and the Public Interest*, (Routledge, 2015) 1 (noting that, 'The United Nations Centre on Transnational Corporations ... was established in 1975 and abolished in 1992. It was an early effort by the UN to address the overlapping issues of national sovereignty, corporate responsibility, and global governance.').

²⁹ Hamdani and Ruffing, *ibid*, 8 (noting that, '...The Washington Post (on 22 March 1972) and The New York Times (on 21-23 March 1972) reported that the Central Intelligence Agency of the United States had plotted with the International Telephone and Telegraph Company (ITT) to prevent Allende from becoming the first democratically elected Marxist president in Latin America. The US state department denied the matter but the news reports – which were credible – had already created a stir and the UN was an opportune forum to rebuke America.'). See also, Sauvant, note 27, 13 (noting that, 'The trigger was ITT's interference in Chile's domestic policy, which eventually contributed to the overthrow of President Salvador Allende and politicized the issue further. President Allende drew attention to this interference in a speech in the General Assembly of the United Nations in 1972 and galvanized the international community to take action to address, and check, the "economic power, political influence and corrupting action" of [Transnational Corporations].').

the negotiations on the code also reflected the wider political context of the 1970s which was characterised by the ascendancy of developing countries that had just gained independence, economic nationalism, and demands for a New International Economic Order (NIEO).³⁰ Ultimately, aided by the inability of developing countries to maintain a stable coalition, the collapse of the Soviet bloc, and the emergence of the Washington Consensus, the negotiations to adopt the Code were unsuccessful and, by 1996, the code was dropped from the UN agenda.³¹

³⁰ Hamdani and Ruffing, *ibid*, 7 (noting that, ‘Transnational corporations were placed on the UN agenda in the 1970s. It was [a] period of economic nationalism, Cold War politics, covert activity, and political jingoism. International business was seen as a facilitator, a victim, and a threat.’). See also, Sauviant, note 27, 13-16 (noting that, ‘[Transnational Corporations] were seen as having a substantial impact on individual national economies and international economic relations, and there was widespread suspicion that ... this impact was negative in terms of the distribution of benefits and the ability of indigenous firms to grow and prosper. Around the same time, most developing countries had emerged from colonialism, consolidated their independence, had become members of the United Nations, and began to assert themselves in international fora ... Nationalizations reached their peak in the early 1970s ... The confluence of these factors was reflected in the drive of the developing countries, supported by the socialist countries, to establish a New International Economic Order (NIEO) ... It was in this context that the Commission on Transnational Corporations (comprising representatives of governments) and UNCTC (as the secretariat of the Commission) were established, and the drive began to deal with [Transnational Corporations] and their FDI at the international level.’).

³¹ David Coleman has identified a number of reasons for the failure of the negotiations on the Code. According to Coleman, ‘There are a variety of reasons why the internationalised code of conduct on [Transnational Corporations] activities failed ... The first set of reasons relates to the extended political timeline of the code ... Perpetually held in a draft state, a lack of consensus within the Commission effectively foiled progress by filibuster. The political nature of the proposed code of conduct further limited the likelihood of finalisation as years passed. Linked to the NIEO in 1974, it was perhaps inevitable that the ... code of conduct would suffer equally from the slow demise of the NIEO in the 1980s ... Part of the code’s failure also came from an eroding

Subsequently, in the late 1990s, another attempt was made to develop norms aimed at the imposition of binding human rights obligations on corporate actors. This second attempt occurred via the UN Sub-Commission on the Promotion and Protection of Human Rights through its Working Group on the Working Methods and Activities of Transnational Corporations which was established in 1998.³² The Working Group eventually produced a document which was approved by the Sub-Commission in 2003 i.e. the ‘Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with regard to Human Rights’ (hereinafter, Norms).³³

consensus in the “Third World coalition” through the differential wealth and growth opportunities in developing countries ... With vastly different economic realities in member countries, the G77 was not able to maintain a stable coalition on issues related to trade and foreign investment ... The collapse of the Soviet bloc in the late 1980s contributed to a rise in free-market triumphalism. With the United States emerging as the sole superpower, the “Washington Consensus” presented the market economy as the dominant paradigm.’ See, David Coleman, ‘The United Nations and Transnational Corporations: From an Inter-nation to a “Beyond-state” Model of Engagement,’ (2003) 17:4 *Global Society* 339, 349-350.

³² See, Pini Pavel Miretski and Sascha-Dominik Bachmann, ‘The UN “Norms on the Responsibility of Transnational Corporations and Other Business Enterprises with regard to Human Rights”: A Requiem,’ (2012) 17:1 *Deakin Law Review* 5, 6.

³³ Sub-Commission on the Promotion and Protection of Human Rights, ‘Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights,’ UN ESCOR, 55th sess, 22nd mtg, Agenda Item 4, UN Doc E/CN.4/Sub.2/2003/12/Rev.2 (13 August 2003); David Weissbrodt and Muria Kruger, ‘Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights,’ (2003) 97 *American Journal of International Law* 901; David Kinley and Rachel Chambers, ‘The UN Human Rights Norms for Corporations: The Private Implications of Public International Law,’ (2006) 6:3 *Human Rights Law Review* 447.

The Norms acknowledged that states bear the primary responsibility to promote, fulfil, respect, ensure respect of, and protect human rights. However, the Norms further provided that '[w]ithin their respective spheres of activity and influence, transnational corporations and other business enterprises have the obligation to promote, secure the fulfilment of, respect, ensure respect of and protect human rights.'³⁴ The Norms were however opposed by a number of states and corporate actors.³⁵ The former UN Commission on Human Rights (now the UN Human Rights Council) subsequently noted that the Norms had no legal status³⁶ and the Norms were subsequently abandoned.³⁷

³⁴ Article 1 of the Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with regard to Human Rights.

³⁵ Miretski and Bachmann, note 32, 8-9 (noting that, 'explicit support for the Norms was accompanied by often fierce opposition from various states and the majority of the business community ... Most states expressed strong reservations, emphasising their determination not to depart from the traditional framework of international law, which stresses the central and pivotal role of the state as a legal subject of public international law.'). See also, John Ruggie, *Just Business: Multinational Corporations and Human Rights*, (WW Norton & Co., 2013), xvii (noting that, 'The Norms triggered a deeply divisive debate between human rights advocacy organizations and the business community. Advocates were fervently in favor because the Norms proposed making these obligations binding on companies directly under international law. Business vehemently opposed what it described as "the privatization of human rights," transferring to companies obligations that they believed belonged to states.').

³⁶ See, UNCHR, 'Responsibilities of Transnational Corporations and Related Business Enterprises with Regard to Human Rights,' E/CN.4/Dec/2004/116 (20 April 2004) (affirming that the Norms had 'not been requested by the Commission and, as a draft proposal, has no legal standing, and that the Sub-Commission should not perform any monitoring function in this regard.').

³⁷ Miretski and Bachmann, note 32, 9. Miretski and Bachmann have identified three reasons for the demise of the Norms: 'Firstly, the fact that a large part of the Norms constituted a further development of existing

Even though the Norms faced significant opposition, there was an acknowledgement from both states and corporate actors that there was a need for some clarification on the human rights responsibilities of corporate actors.³⁸ As Ruggie notes, in the face of campaigns from advocacy groups and lawsuits, ‘business itself felt a need for greater clarity regarding their human rights responsibilities from some reasonably objective and authoritative source.’³⁹ Moreover, probably due to the failure of both the Code and the Norms, states were sceptical about the prospects of making any progress in this regard via an intergovernmental process.⁴⁰ Thus, a special mandate for an individual expert on this issue was established by the Commission on Human Rights in 2005.⁴¹ The Commission specifically requested the UN Secretary-General to appoint the expert as a ‘Special Representative on the issue of human rights and transnational corporations and other business enterprises.’⁴² Kofi Annan, the then

international norms, rather than actual codification of existing international law, enabled critics of the Norms to argue their incompatibility, as legal analogies, with otherwise positivist foundations of international law. Secondly, the fact that the Norms assigned an important legal role to [Transnational Corporations] ... rather than to the traditional addresses of international law, the states, was problematic ... Finally, inherent contradictions within the Norms themselves and a vagueness in their overall nature and applicability helped to foster opposition against their adoption.’). Ibid, 10.

³⁸ John Ruggie, *Just Business: Multinational Corporations and Human Rights*, note 35, xvii.

³⁹ Ibid, xvii-xviii.

⁴⁰ Ibid, xviii.

⁴¹ Commission on Human Rights, ‘Promotion and Protection of Human Rights,’ E/CN.4/2005/L.87 (15 April 2005).

⁴² Ibid.

UN Secretary-General, subsequently appointed John Ruggie as the Special Representative in July 2005.⁴³

Unlike the drafters of the Norms, Ruggie's objective was not to develop a legally binding instrument but a politically authoritative formula that could form the basis for further legal developments.⁴⁴ In his work, Ruggie was guided by what he termed principled pragmatism.⁴⁵ In this regard, in his 2006 interim report, Ruggie stated that:

... the Special Representative of the Secretary-General takes his mandate to be primarily evidence-based. But insofar as it involves assessing difficult situations that are themselves in flux, it inevitably will also entail making normative judgements. In the Special Representative's case, the basis for those judgements might best be described as a principled form of pragmatism: an unflinching commitment to the principle of strengthening the promotion and protection of human rights as it relates to business, coupled with a pragmatic attachment to what works best in creating change where it matters most - in the daily lives of people.⁴⁶

In March 2011, Ruggie submitted his final report to the UN Human Rights Council. This report, which contained Ruggie's *Guiding Principles on Business and Human Rights*:

⁴³ John Ruggie, *Just Business: Multinational Corporations and Human Rights*, note 35, xviii.

⁴⁴ Ibid, xlvi.

⁴⁵ Ibid, xlii.

⁴⁶ UN Economic and Social Council, Commission on Human Rights, 'Promotion and Protection of Human Rights: Interim report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises,' E/CN.4/2006/97 (22 February 2006), para 81.

*Implementing the United Nations 'Protect, Respect and Remedy' Framework*⁴⁷ was endorsed by the UN Human Rights Council in June 2011.

Ruggie's Guiding Principles rests on three pillars: the duty of states to respect, protect and fulfil human rights; the duty of corporate actors to comply with all applicable laws and to respect human rights; and the need to provide appropriate and effective remedies to those whose rights have been breached.⁴⁸ Essentially, the Guiding Principles provide that business enterprises should respect human rights and 'this means that they should avoid infringing on the human rights of others and should address the adverse human rights impacts with which they are involved'.⁴⁹ It also provides that the responsibility to respect human rights requires that business enterprises 'avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur'.⁵⁰

Thus, unlike the Norms which sought to impose the responsibility to respect, protect and fulfil human rights on corporate actors, Ruggie's Guiding Principles identified the responsibility to respect as the baseline responsibility of corporate actors. In other words, states remain the primary duty bearers under international human rights law although corporate actors also have a duty to respect human rights. While the Guiding Principles are non-binding, they have been endorsed by the UN Human Rights Council and they can serve as a basis for further legal developments in this regard.⁵¹ In addition, while the Guiding

⁴⁷ Human Rights Council, 'Guiding Principles,' note 2.

⁴⁸ Ibid, 6.

⁴⁹ Ibid Principle 11.

⁵⁰ Ibid Principle 13(a).

⁵¹ Ibid para 13 (noting that, 'Council endorsement of the Guiding Principles, by itself, will not bring business and human rights challenges to an end. But it will mark the end of the beginning: by establishing a common

Principles do not create new obligations under international law, they elaborate on the implications of existing standards and practices for states and corporate actors.⁵²

Beyond the Guiding Principles which deal with the responsibility of corporate actors in relation to human rights at a general level, significant work has also been done in terms of defining the specific responsibilities of pharmaceutical companies in relation to the right to health. In 2008, Paul Hunt, the UN Special Rapporteur on the right to the highest attainable standard of health between 2002 and 2008, presented his report to the UN General Assembly. Hunt's report contains the *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, a set of 47 guidelines on the right to health responsibilities of pharmaceutical companies.⁵³ Taking the view that merely urging pharmaceutical companies to comply with their right-to-health responsibility is unhelpful, Hunt's goal in developing the Guidelines was to clarify and explain the human rights responsibility of pharmaceutical companies in relation to access to medicines.⁵⁴

global platform for action, on which cumulative progress can be built, step-by-step, without foreclosing any other promising longer-term developments.').

⁵² Ibid para 14 (noting that, 'The Guiding Principles' normative contribution lies not in the creation of new international law obligations but in elaborating the implications of existing standards and practices for States and businesses; integrating them within a single, logically coherent and comprehensive template; and identifying where the current regime falls short and how it should be improved.').

⁵³ Hunt, 'Guidelines,' note 3. See also, Paul Hunt and Rajat Khosla, 'Are Drug Companies Living up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008),' (2010) 7 *PLoS Medicine* 1; Lee and Hunt, note 4, 221.

⁵⁴ See, Rajat Khosla and Paul Hunt, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines,' in Lisa Forman and Jillian Clare Kohler (eds.), *Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility*, (University of Toronto Press, 2012), 37-38.

Prior to presenting the Guidelines in 2008, Hunt had earlier released a draft version of the Guidelines in September 2007 and the draft was available for comments from members of the public till May 2008.⁵⁵ The draft was aimed at providing assistance to both pharmaceutical companies and actors who intend to monitor the performance of pharmaceutical companies in relation to access to medicines.⁵⁶ Based on the comments received from several actors (including states, pharmaceutical companies, NGOs, and academics), the draft was revised and the final version of the Guidelines was presented to the UN General Assembly in 2008.⁵⁷

The Hunt Guidelines is a set of 47 Guidelines on the right to health responsibilities of pharmaceutical companies in relation to access to medicines.⁵⁸ Essentially, the Guidelines include responsibilities for ‘transparency, management, monitoring and accountability, pricing, and ethical marketing, and against lobbying for more protection in intellectual property laws, applying for patents for trivial modifications of existing medicines, inappropriate drug promotion, and excessive pricing’.⁵⁹

However, as noted earlier, while the Guiding Principles emphasize the baseline responsibility of corporate actors to respect human rights, the Hunt Guidelines go beyond this baseline responsibility to respect human rights. In an article published in 2012 by Joo-Young Lee and Paul Hunt, the relationship between the Guiding Principles and the Hunt Guidelines was examined and the authors stated that,

⁵⁵ Ibid, 29.

⁵⁶ Ibid.

⁵⁷ Ibid, 30.

⁵⁸ Hunt, ‘Guidelines,’ note 3. See also, Hunt and Khosla, note 53, 1; Lee and Hunt, note 4, 221.

⁵⁹ Hunt and Khosla, note 53, 1.

...taking into account the right-to-health framework, which is based on the dignity and well-being of individuals and communities, as well as globally recognized standards, the *Guidelines for Pharmaceutical Companies* encompass, but also look beyond, the corporate responsibility to respect. In our view, an examination of human rights responsibilities beyond the duty to respect is critically important because the pharmaceutical sector has highly distinctive functions directly impacting upon the life, health, and prosperity of countless individuals and communities.⁶⁰

The attempt by Hunt to go beyond the baseline responsibility of corporate actors to respect human rights in the Guidelines led to an overlap, in some of the Guidelines, between the responsibility of states to respect, protect, and fulfil the right to health and the baseline responsibility of pharmaceutical corporations to respect the right to health as specified in the Guiding Principles. As Suerie Moon rightly contends, ‘it is useful to distinguish between those guidelines that primarily relate to the responsibility to respect and those that may relate to additional responsibilities’.⁶¹ Moon identifies three reasons why it is useful to draw this distinction.

Firstly, ‘if “respect” forms the baseline, then it is important to ensure that companies are indeed living up to this most fundamental responsibility’ and distinguishing between the responsibility to respect and other responsibilities helps to ‘focus attention on the most fundamental responsibilities of industry’.⁶² Secondly, ‘conflating the responsibilities of state and non-state actors risks detracting attention away from state obligations, making it easier for governments to shirk their own obligations’.⁶³ Thirdly, ‘the limited resources of civil

⁶⁰ Lee and Hunt, note 4, 224 (*italics in the original*).

⁶¹ Moon, note 5, 37.

⁶² *Ibid.*

⁶³ *Ibid.*

society organizations, journalists, and other watchdog entities underscore the importance of getting the baseline right, allowing such groups to focus their energies on holding companies accountable for at least their most basic human rights responsibilities, and governments for theirs'.⁶⁴

What follows below is an analysis of some of the provisions of the Hunt Guidelines and an attempt to distinguish between the Guidelines that fall within the baseline responsibility of pharmaceutical companies to respect human rights (in accordance with the Guiding Principles) and those that fall outside the scope of the baseline responsibility of pharmaceutical companies to respect human rights. Importantly, the focus of the analysis below is not on all the provisions contained in the Hunt Guidelines, rather the focus will be on the Guidelines that specifically deal with facilitating access to affordable medicines.

3. CLARIFYING THE RIGHT TO HEALTH RESPONSIBILITIES OF PATENT-OWNING PHARMACEUTICAL COMPANIES

A. Hunt Guidelines 1-5: General Guidelines within the Scope of the Baseline Responsibility of Pharmaceutical Companies to Respect the Right to Health

According to Guideline 1 of the Hunt Guidelines, pharmaceutical companies 'should adopt a human rights policy statement which expressly recognizes human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company'. Guideline 2 further provides that pharmaceutical companies 'should integrate human rights, including the right to the

⁶⁴ Ibid.

highest attainable standard of health, into the strategies, policies, programmes, projects and activities of the company’. Guideline 3 goes on to provide that a pharmaceutical company ‘should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled’ and Guideline 4 further provides that pharmaceutical companies ‘should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health’.

These first four Guidelines are broadly consistent with the baseline responsibility of pharmaceutical companies to respect human rights (including the right to health) as specified in the Guiding Principles.⁶⁵ As Hunt pointed out in his commentary on Guidelines 3 and 4, ‘[t]here are numerous national and international (including regional) legal provisions that safeguard aspects of the right to the highest attainable standard of health’ and ‘[i]t is axiomatic that they must be respected, at all times, by all pharmaceutical companies, in accordance with elementary principles of corporate good governance’.⁶⁶

Guideline 5 provides that ‘[w]henver [a pharmaceutical company is] formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should give particular attention to the needs of disadvantaged individuals, communities and populations, such as children, the elderly and those living in poverty’. It further states that particular attention should be given to ‘the very poorest in all markets’. In his commentary on Guideline 5, Hunt points out that, ‘[e]quality

⁶⁵ Ibid 38 (noting that, the first four Guidelines ‘align closely with the principle of respect and Ruggie’s recommendations on how to operationalize it’.).

⁶⁶ Hunt, ‘Guidelines,’ note 3, 17.

and non-discrimination are among the most fundamental features of international human rights, including the right to the highest attainable standards of health'.⁶⁷ Thus, in the words of Hunt, 'the right to the highest attainable standard of health has a particular preoccupation with disadvantaged individuals, communities and populations, including children, the elderly and those living in poverty'.⁶⁸ According to Hunt, '[a]ll the other Guidelines must be interpreted and applied in the light of Guideline 5, which has fundamental importance'.⁶⁹ This Guideline is equally in accordance with the baseline responsibility of pharmaceutical companies to respect the right to health.

B. Hunt Guidelines 26 and 27: Guidelines on the Responsibility of Pharmaceutical Companies to Respect the Patent Policy Space of States

Guideline 26 provides that pharmaceutical companies 'should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) ... which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports'. It further provides that pharmaceutical companies 'should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing'. In addition, Guideline 27 provides that pharmaceutical companies 'should respect the letter and

⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Ibid.

spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) that recognizes a State's right to protect public health and promote access to medicines for all'.

Guidelines 26 and 27 correspond with the responsibility of pharmaceutical companies to respect human rights⁷⁰ and actually attempt to provide greater depth in relation to what it means for a pharmaceutical company to respect the right to health. The flexibilities contained in the TRIPS Agreement (and affirmed by the Doha Declaration on the TRIPS Agreement and Public Health) permits a country to incorporate what can be termed a model of human rights into its national patent system. The model of human rights demands that any regulatory instrument implemented by a state must not constitute a breach of its international human rights obligations. In this regard, this implies that the design, implementation, interpretation, and enforcement of intellectual property laws at the national level must not be done in a manner that impinges on any of the rights contained in any treaty on human rights to which a state is a party. This applies to the executive, legislative, and judicial arms of government. As Shelton points out, '[h]uman rights obligations fall on all State actors, irrespective of the level or branch of government in which they serve ... Whenever a State organ, official, or public entity violates a guaranteed right, this constitutes a failure of the State's obligation'.⁷¹

The model of human rights is relevant in the context of intellectual property rights because intellectual property rights do have an impact on the enjoyment of a number of human rights.

⁷⁰ Moon, note 5, 38 (noting that, "These guidelines advocate against doing harm (for example, through weakening public policies intended to protect access to medicines), and are therefore closely linked to the principle of "respect."").

⁷¹ Dinah Shelton, *Advanced Introduction to International Human Rights Law* (Cheltenham and Northampton: Edward Elgar, 2014) 191.

For instance, copyright law impacts the enjoyment of the right to education,⁷² trademark law and the right of publicity both impact the enjoyment of the right to freedom of expression.⁷³ More importantly for the purposes of this article, patent law impacts the enjoyment of the right to health (which includes the right to have access to medicines). Patent rights have a direct impact on the right to health, especially in developing countries where pharmaceutical products are priced beyond the reach of poor patients. Patents confer exclusive rights on patent owners and this can lead to the inflation of prices of patented products, and as Joseph notes, this can be ‘problematic as goods that are essential for the enjoyment of human rights, such as new medicines, can be priced out of the reach of poor people’.⁷⁴ It is impossible to resolve the tension between patent rights and access to medicines by relying only on the internal principles contained in intellectual property law.⁷⁵ Therefore, the best way to resolve the tension between patent rights and access to medicines is by using external norms

⁷² Susan Isiko Štrba, *International Copyright Law and Access to Education in Developing Countries: Exploring Multilateral Legal and Quasi-Legal Solutions* (Leiden and Boston: Martinus Nijhoff Publishers, 2012).

⁷³ Eugene Volokh, ‘Freedom of Speech and Intellectual Property: Some Thoughts After *Eldred*, 44 *Liquormart*, and *Bartnicki*’ (2003) 40 *Houston Law Review* 697, 698 (noting that, ‘most intellectual property rules—copyright law, trademark law, right of publicity law, and trade secret law—are speech restrictions: They keep people from publishing, producing, and performing the speech that they want to publish, produce, and perform. The laws may be well motivated and often beneficial, but they are speech restrictions’).

⁷⁴ Sarah Joseph, ‘Trade and The Right to Health’ in Andrew Clapham and Mary Robinson (eds), *Realizing The Right to Health*, Swiss Human Rights Book Series, vol 3 (Zurich: Ruffer & Rub, 2009) 360.

⁷⁵ Amanda Barratt, ‘The Curious Absence of Human Rights: Can the WIPO Development Agenda Transform Intellectual Property Negotiation?’ (2010) 14 *Law, Democracy & Development* 14, 24.

contained in the human rights system and this can be done by incorporating a model of human rights into the patent system.⁷⁶ As Yamin points out,

Human rights law not only offers an alternative paradigm for understanding issues relating to the availability and distribution of medications, it also provides a workable framework for influencing the way in which adjudicative and legislative bodies, as well as other actors, make decisions that affect access to medications ... [T]reaties and statutes relating to trade, competition, intellectual property, or other factors bearing on access to medications can often be ambiguous; in such cases, a human rights framework imposes an obligation to interpret such treaties and legislation in the manner that most fully advances the public's health interests ... Further, human rights provides a set of principles according to which laws, policies and programs can be evaluated and reformed.⁷⁷

Crucially, the statement contained in paragraph 4 of the Doha Declaration to the effect that the TRIPS Agreement should be interpreted and implemented in a manner that supports the right of countries to promote access to medicines offers an avenue for developing countries to preserve their patent policy space.⁷⁸ In other words, paragraph 4 of the Doha Declaration provides a linchpin that developing countries can use to preserve their patent policy space as it sanctions the incorporation of a model of human rights into the design, implementation, interpretation, and enforcement of their national patent laws. Thus, the protection of the right

⁷⁶ As Amanda Barratt points out, human right norms 'provide specific limitations on what is negotiable, while identifying precise minimum conditions that are beyond negotiation.' See, Amanda Barratt, *ibid*, 32.

⁷⁷ Alicia E Yamin, 'Not Just A Tragedy: Access to Medications as A Right under International Law' (2003) 21 *Boston University International Law Journal* 325, 327-329.

⁷⁸ See, WTO Ministerial Conference, 'Declaration on the TRIPS Agreement and Public Health', Adopted on 14 November 2001, WT/MIN(01)/DEC/2, (20 November 2001) para 4.

to health and the provision of greater access to medicines through the use of flexibilities such as the exclusion of new forms of known drugs from patent protection, compulsory licensing, parallel importation, and regulatory review exemption for producers of generic drugs, pursuant to a model of human rights is compatible with the text of the TRIPS Agreement in the context of the Doha Declaration.

Patent-owning pharmaceutical companies will therefore be failing to comply with their baseline responsibility to respect the right to health when they refuse to respect the rights of countries to utilize the flexibilities contained in the TRIPS Agreement such as compulsory licensing and parallel importation. Furthermore, a pharmaceutical company that fails to respect the provisions of paragraph 4 of the Doha Declaration will not be acting in accordance with its responsibility to respect the right to health. Nevertheless, for the right to health responsibilities of pharmaceutical companies in this regard to be meaningful, it is imperative for states to first take seriously their own obligation to respect, protect and fulfil the right to health by incorporating a model of human rights into the design, implementation, interpretation, and enforcement of their national patent laws.

C. Guidelines 30-32: Guidelines Touching on the Responsibilities of Both States and Pharmaceutical Companies with regard to the Right to Health

Guideline 30 provides that, as part of their access to medicines policy, pharmaceutical companies ‘should issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines’. In addition, Guideline 31

provides that, as a minimum, pharmaceutical companies ‘should consent to National Drug Regulatory Authorities using test data (i.e., [they] should waive test data exclusivity) in least developed countries and also when a compulsory licence is issued in a middle-income country’. Furthermore, Guideline 32 provides that pharmaceutical companies ‘should not apply for patents for insignificant or trivial modifications of existing medicines’ in low-income and middle-income countries.

In his commentary on Guidelines 30 and 31, Hunt points out that voluntary licences ‘have a vital role to play in extending access to medicines’ and that because ‘data exclusivity has the potential to hinder access to medicines, companies should waive such exclusivity in all appropriate cases’.⁷⁹ Hunt further states that ‘while Guideline 31 identifies two occasions when the company should waive data exclusivity, there will be other occasions when a waiver is appropriate as a way of enhancing access to medicines for disadvantaged individuals, communities and populations’.⁸⁰ Commenting on Guideline 32, Hunt states that, access to medicines ‘may be hindered when a company applies for a patent for improvements to an existing medicine’ and that ‘Guideline 32 is designed to mitigate this problem in low-income and middle-income countries’.⁸¹

Moon argues that Guideline 30 (specifying that pharmaceutical companies should issue non-exclusive voluntary licences in low-income and middle-income countries) falls within an area that is ‘conceptually closer to “fulfilling” the right to health than “respecting” it’.⁸² Since the responsibility to fulfil human rights falls primarily on states, Moon contends that ‘conductive

⁷⁹ Hunt, ‘Guidelines,’ note 3, 22.

⁸⁰ Ibid.

⁸¹ Ibid.

⁸² Moon, note 5, 40.

public policy is likely to be required to shape firm behaviour towards fulfillment'.⁸³ According to Moon, 'while guideline 30 calls on firms to issue voluntary licenses on all medicines in low- and middle-income countries, firms are unlikely to do so if it will significantly hurt their bottom-line' and that because 'middle-income countries are projected to be the major source of revenue growth for the industry in the coming decade, it is highly unlikely that for-profit entities will voluntarily sign away monopoly rights in these countries'.⁸⁴

It will however appear that, contrary to Moon's contention, Guideline 30 falls within both the state responsibility to protect and fulfil the right to health on the one hand, and the responsibility of pharmaceutical companies to respect the right to health on the other hand. A state has the responsibility to protect and fulfil the right to health by incorporating a model of human rights into its national patent law. In this regard, a state can stipulate in its national patent law that patent owners must satisfy the reasonable requirements of the public with respect to the patented product and that patented products (including patented pharmaceutical products) must be sold at a price that is reasonably affordable. A pharmaceutical company can respect the right to health in this regard by complying with the provisions of such national patent law and by taking steps to facilitate greater access to its patented pharmaceutical products through the grant of voluntary licences to local generic drug producers. Respecting the right to health in this regard may not necessarily require the grant of voluntary licences on all medicines in developing countries as demanded by Guideline 30. Taking reasonable steps to ensure that patented drugs are not sold at exorbitant prices should suffice.

⁸³ Ibid.

⁸⁴ Ibid.

Thus, where a state has taken steps to protect and fulfil the right to health by incorporating a model of human rights into its national patent law, a pharmaceutical company has a baseline responsibility to respect the right to health by complying with the national patent law (as specified in Guideline 3). For the responsibility of pharmaceutical companies in this regard to be meaningful, states have to first amend their patent law to require that patented medicines be sold at reasonably affordable prices, thereafter pharmaceutical companies have the responsibility to comply with the law.

India is a very good example of a country that has incorporated a model of human rights into its national patent law. It can thus serve as a useful model for other countries in this regard. For instance, section 84 of the Indian Patents Act provides for the grant of a compulsory licence on the following grounds: (i) the failure to satisfy the reasonable requirements of the public with respect to the patented invention;⁸⁵ or (ii) failure to make the patented invention available to the public at a reasonably affordable price;⁸⁶ or (iii) failure to work the patented invention in the territory of India.⁸⁷ Provisions such as these are permitted by Article 31 of the TRIPS Agreement (which deals with the grant of compulsory licences) and the Doha Declaration on the TRIPS Agreement and Public Health. Thus, since pharmaceutical companies have a baseline responsibility to respect the right to health by complying with national laws (Guideline 3) and by also respecting the right of countries to use the flexibilities contained in the TRIPS Agreement (Guideline 26), pharmaceutical companies therefore have to ensure that they satisfy the requirements of provisions such as section 84 because failure to comply may result in their patented pharmaceutical product being compulsorily licensed to another pharmaceutical company.

⁸⁵ Section 84(1)(a) of the Indian Patents Act.

⁸⁶ Section 84(1)(b) of the Indian Patents Act.

⁸⁷ Section 84(1)(c) of the Indian Patents Act.

Bayer's failure to comply with the requirements of section 84 resulted in the grant of a compulsory licence to Natco with respect to Bayer's patented drug, Nexavar.⁸⁸ One of the ways by which Bayer could have avoided the grant of a compulsory licence in this case was by issuing a voluntary licence to a local generic drug company in India. Thus, in certain cases, it may actually be in the best interests of a pharmaceutical company to issue a voluntary licence in a middle-income country.

It is noteworthy that Gilead Sciences opted to issue voluntary licences with respect to its blockbuster hepatitis C drug, Solvadi, to seven Indian generic drug manufacturers in 2014.⁸⁹

⁸⁸ See, *Natco v Bayer*, Compulsory License Application No. 1 of 2011, (decision of the Indian Controller of Patents, 9 March 2012); *Bayer v Union of India & Others*, OA/35/2012/PT/MUM, (decision of the Indian Intellectual Property Appellate Board, 4 March 2013); *Bayer Corporation v Union of India and Ors.*, Writ Petition No. 1323 of 2013 (decision of the Bombay High Court, 15 July 2014). Bayer's subsequent petition to the Indian Supreme Court for a special leave to appeal against the judgment of the Bombay High Court was dismissed by the Supreme Court. See, *Bayer Corporation v Union of India & Ors.*, Petition(s) for Special Leave to Appeal (C) NO(S). 30145/2014 (decision of the Indian Supreme Court, 12 December 2014).

⁸⁹ See, Gilead, 'Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries' (15 September 2014), <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>, (accessed 12 March 2017), (noting that Gilead 'signed non-exclusive licensing agreements with seven India-based generic pharmaceutical manufacturers to expand access to its chronic hepatitis C medicines in developing countries. The agreements allow the companies – Cadila Healthcare Ltd., Cipla Ltd., Hetero Labs Ltd., Mylan Laboratories Ltd., Ranbaxy Laboratories Ltd., Sequent Scientific Ltd. and Stride Arcolab Ltd. – to manufacture sofosbuvir and the investigational single tablet regimen of ledipasvir/sofosbuvir for distribution in 91 developing countries.'). In January 2015, Gilead expanded the licensing agreements to include its investigational sofosbuvir/GS-5816 regimen which 'would become the first pan-genotypic, all-oral single tablet regimen for HCV'. Gilead stated that '[a] pan-genotypic therapeutic option is particularly important for developing countries, where genotype testing is often unreliable or not readily available'. It further stated that

Under the terms of the voluntary licence, the Indian companies are permitted to distribute the drug in 91 developing countries and these countries ‘account for more than 100 million people living with hepatitis C, representing 54% of the total global infected population’.⁹⁰

Furthermore, under the terms of the voluntary licence, ‘the Indian companies [will] receive a

eight Indian-based generic manufacturers, including Biocon Ltd., now hold licences to manufacture its HCV medicines. See, Gilead, ‘Gilead Expands Hepatitis C Generic Licensing Agreements to Include Investigational Pan-Genotypic Agent’ (26 January 2015), <http://www.gilead.com/news/press-releases/2015/1/gilead-expands-hepatitis-c-generic-licensing-agreements-to-include-investigational-pangenotypic-agent>, (accessed 12 March 2017).

⁹⁰ Gilead (2014), note 89. However, concerns have been expressed about the exclusion of many middle-income countries from the list of countries covered by the voluntary licence agreements. See, Medicines Sans Frontières – Access Campaign, ‘MSF Access Campaign Response to Gilead’s Deal With Generic Companies for Sofosbuvir and Ledipasvir’ (15 September 2014), <http://www.msfacecess.org/content/msf-access-campaign-response-gilead%E2%80%99s-deal-generic-companies-sofosbuvir-and-ledipasvir> (accessed 12 March 2017), (noting that, ‘Although the Gilead agreements will allow some generic companies to market generic versions of both drugs in approximately 90 countries regardless of the patent status in those countries, most of the countries expected to be included in the license agreements are low-income economies, many of which may not have had patent protection on these new drugs in the first place. Hepatitis C is especially prevalent in middle-income countries – with approximately 73% of the burden in these countries – but disappointingly many of these countries remain excluded from accessing both Gilead’s lowest price and the generic versions licensed by these agreements.’). For a contrary view see, James Love, ‘The Gilead HCV License: Glass Half Empty, or Half Full?’, *Knowledge Ecology International*, (16 September 2014), <http://www.keionline.org/node/2083> (accessed 12 March 2017), (noting that, ‘While I can understand people wanting Gilead to have done more, and we think they could have easily added more Latin America, North Africa and Asian countries, it is not as if the licenses were unimportant. Gilead was asked by KEI and other NGOs to create a voluntary licensing territory that was big enough to induce entry by several generic companies, and they did that. Gilead was also asked to provide a path for countries left out of the license to receive imports from the generic producers, and they did that -- by providing language in the license that allows producers to supply other countries under compulsory licenses, or in countries with no patents.’).

complete technology transfer of the Gilead manufacturing process to enable them to scale up production as quickly as possible’.⁹¹ In addition, the licensees are at liberty to set their own prices for their generic drugs though they are required to pay a royalty on sales to Gilead to ‘support product registrations, medical education and training, safety monitoring and other essential business activities’.⁹²

⁹¹ Gilead (2014), note 89.

⁹² Ibid. Interestingly, on 13 January 2015, Gilead’s application for a patent was initially rejected by the Indian Patent Office on the grounds of a failure to satisfy the requirements of section 3(d) of the Indian Patents Act. A pre-grant opposition had been filed against Gilead’s patent application by an Indian generic drug company, Natco Pharma Ltd and two other NGOs: Delhi Network of Positive People (DNP+) and Initiative for Medicines, Access and Knowledge (I-MAK). See, *In the Matter of Application No. 6087/DELNP/2005*, decision of the Deputy Controller of Patents and Designs, (13 January 2015). The decision of the Indian Patent Office was hailed by advocates for access to medicines. See, Medecins Sans Frontieres – Access Campaign, ‘Gilead Denied Patent for Hepatitis C Drug Sofosbuvir in India’ (14 January 2015), <http://www.msfaccess.org/about-us/media-room/press-releases/gilead-denied-patent-hepatitis-c-drug-sofosbuvir-india> (accessed 12 March 2017), (noting that, ‘With the patent being denied, other companies that have not signed the licence are now free to produce. Entry by additional generic manufacturers should increase the open competition needed to bring prices down dramatically, especially in those countries that have been excluded from the voluntary licence agreement, and thereby increase access to the medicine.’). However, Gilead filed an appeal against the decision of the Indian Patent Office. On 30 January 2015, the Delhi High Court remanded the case back to the Indian Patent Office for a fresh decision on procedural grounds. Among other things, Gilead had contended before the High Court that it had not been given the opportunity to respond to the objections raised in the pre-grant oppositions. See, *Gilead Pharmasset, LLC. v Union of India*, WP(C) 687/2015 and CM No. 1222/2015 (decision of the High Court of Delhi at New Delhi, 30 January 2015). In its subsequent decision, the Indian Patent Office reversed its earlier decision and dismissed all the pre-grant opposition filed against Gilead’s patent application. See, *Gilead Pharmasset LLC. USA v Optimus Pharma Ltd and others, In the matter of Patent Application No. 6087/DELNP/2005*, decision of the Deputy Controller of Patents and Designs, (9 May 2016).

In the same vein, Bristol-Myers Squibb (BMS) equally announced in 2014 that it has ‘initiated discussions with government health authorities and other stakeholders in a number of developing countries to facilitate access to daclatasvir [its own Hepatitis C drug]’.⁹³ BMS stated that it was going to work with licensed generic manufacturers in 90 countries to supply licensed versions of daclatasvir.⁹⁴

Furthermore, AbbVie, Bristol-Myers Squibb, Hoffman-La Roche, Gilead Sciences, and ViiV Healthcare (a joint venture of GlaxoSmithKline, Pfizer and Shionogi) have all signed licence agreements with the UN backed Medicines Patent Pool (MPP).⁹⁵ The MPP, which was established in 2010 with support from UNITAID, works ‘to increase access to HIV, viral hepatitis C and tuberculosis treatments in low- and middle-income countries.’⁹⁶ The MPP works in partnership with a range of stakeholders as it ‘partners with governments, industry, civil society, international organisations, patient groups and other stakeholders to forecast, prioritise and license needed medicines,’ and it also ‘encourages generic manufacture and the development of new formulations through patent pooling.’⁹⁷ Notably, in November 2015, the MPP ‘signed a licensing agreement with Bristol-Myers Squibb (BMS) for hepatitis C

⁹³ See, Carly Helfand, ‘HCV Developing World Strategy,’ *FiercePharma*, (3 November 2014), <http://www.fiercepharma.com/press-releases/hcv-developing-world-strategy> (accessed 12 March 2017).

⁹⁴ Ibid.

⁹⁵ Medicines Patent Pool, ‘Company Engagement’, <http://www.medicinespatentpool.org/company-engagement/> (accessed 12 March 2017).

⁹⁶ Medicines Patent Pool, ‘About the MPP’, <http://www.medicinespatentpool.org/about/> (accessed 12 March 2017).

⁹⁷ Ibid.

medicines daclatasvir (DCV) allowing generic manufacturer[s] to develop and distribute daclatasvir in 112 low- and middle-income countries.’⁹⁸

Moon rightly contends that Guideline 31 (dealing with the waiver of data exclusivity) and Guideline 32 (dealing with refraining from the patenting of trivial modifications of known drugs, otherwise known as ever-greening) ‘fall squarely into a gray area, involving both the state duty to protect [human rights] and business responsibility to respect [human rights]’ because they ‘call on firms to refrain from certain actions that would undermine access ... but are likely to require state action, especially when significant profits are at stake.’⁹⁹ According to her, even though Guidelines 31 and 32 are aimed at addressing measures that ‘can strengthen the monopoly on a medicine and thereby increase profits’, the prevention of ‘such expanded monopolies (and related price increases) is more likely if states simply disallow data exclusivity and patents on trivial modifications of existing medicines in their national laws, as allowed under TRIPS.’¹⁰⁰

It is only necessary to add that, where a state has fulfilled its responsibility to protect the right to health by incorporating the necessary flexibilities into its national patent law, the measures addressed by both Guidelines 31 and 32 can be dealt with under the scope of Guideline 3 (which specifies that pharmaceutical companies should comply with the national laws of the country where they operate), Guideline 26 (which specifies that pharmaceutical companies should respect the right of countries to utilize the flexibilities contained in the TRIPS

⁹⁸ Medicines Patent Pool, ‘Company Engagement’, note 95. According to the MPP, as of November 2016, it ‘had signed sub-licensing agreements with fifteen generic manufacturers: Aurobindo Pharma Limited, Beximco, Cipla, Desano, Emcure Pharmaceuticals, Hetero Labs, Huahai Pharmaceutical, Laurus Labs, Lupin, Micro Labs, Mylan, Natco, Sandoz, Strides Arcolab and Zydus Cadila.’ Ibid.

⁹⁹ Moon, note 5, 39.

¹⁰⁰ Ibid 40.

Agreement), and Guideline 27 (which specifies that pharmaceutical companies should respect the letter and spirit of the Doha Declaration that recognizes a state's right to protect public health and promote access to medicines for all).

In other words, while a state has the responsibility to protect the right to health of its citizens by incorporating a model of human rights into its national patent system through the adoption of flexibilities such as the exclusion of data exclusivity and the prohibition of the grant of patents on trivial modifications of previously known drugs, the baseline responsibility of pharmaceutical companies is to respect the right of countries to utilize these flexibilities and to equally comply with them. It is counter-intuitive to expect that the majority of pharmaceutical companies will support the waiver of data exclusivity or refrain from obtaining patents on trivial modifications of previously known drugs in the absence of national legislation in this regard.¹⁰¹ In reality, even in a country, such as India, where the Patents Act in section 3(d) prohibits the grant of patents on new forms of known drugs, pharmaceutical companies still make attempts to apply for patents on these types of drugs.¹⁰²

D. Guidelines 33 and 34: Guidelines Relating to the Pricing of Pharmaceutical Products – Another set of Guidelines Touching on the Responsibilities of Both States and Pharmaceutical Companies with regard to the Right to Health

¹⁰¹ Anand Grover and others, 'Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability under the Right to Health' (2012) 40 *Journal of Law, Medicine & Ethics* 234, 244 (noting that, 'rights-respecting behavior and activities directed toward promoting human rights do not consistently align with profit-seeking corporate behavior.').

¹⁰² This is evidenced by the case of *Novartis AG v Union of India & Ors*, Civil Appeal Nos. 2706-2716 of 2013, (Supreme Court of India, 1 April 2013).

Guidelines 33 and 34 deal with the pricing of medicines. According to Guideline 33, '[w]hen formulating and implementing its access to medicines policy, the company should consider all the arrangements at its disposal with a view to ensuring that its medicines are affordable to as many people as possible.' It further provides that in line with Guideline 5, 'the company should give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities and populations, including those living in poverty and the very poorest in all markets' and '[t]he arrangements should include, for example, differential pricing between countries, differential pricing within countries, commercial voluntary licences, not-for-profit voluntary licences, donation programmes, and public-private partnerships.' In addition, Guideline 34 provides that such 'arrangements should take into account a country's stage of economic development, as well as the differential purchasing power of populations within a country' and that '[t]he same medicine, for example, may be priced and packaged differently for the private and public sectors within the same country.'

In his commentary, Hunt recognized that pharmaceutical companies have a responsibility to enhance shareholder value but he stated that they also have 'a human rights responsibility to extend access to medicines for all, including disadvantaged individuals, communities and populations' and that in this context, 'pricing has a critical role to play'.¹⁰³ Hunt further states that '[l]ower prices do not necessarily mean lower profits' and that '[s]ometimes the goal of enhancing access to medicines coincides with commercial interests'.¹⁰⁴ According to Hunt, '[t]here are numerous arrangements that may reduce prices and increase sales, some of which

¹⁰³ Hunt, 'Guidelines,' note 3, 23.

¹⁰⁴ Ibid.

are mentioned in Guidelines 33 and 34 and '[b]ecause the lives and health of millions are at stake, companies must approach such arrangements with urgency, creativity and boldness'.¹⁰⁵

Moon however contends that '[w]hile company efforts to decrease the price of medicines are welcome, ensuring that price is not a barrier to access falls far beyond the responsibility to respect – in some cases, this would imply negative prices for the poorest populations; nor do the policies prescribed in the guidelines necessarily ensure affordability'.¹⁰⁶ According to Moon, 'ensuring affordability falls under the obligation of states to protect and fulfill the right to access to medicines, and is arguably more likely when governments deploy a range of policy tools for this purpose, such as price negotiations, price controls, generic promotion, compulsory licensing, competition-enhancing policies, and subsidies'.¹⁰⁷ In Moon's opinion, 'for the most lucrative medicines in the fast-growing (but highly unequal) middle-income countries, affordability is unlikely to be achieved without decisive public policy'.¹⁰⁸

It is true that states bear the primary responsibility to protect and fulfil the right to health by taking action to facilitate greater access to essential medicines at affordable prices. It can however be argued that once a state has taken steps towards facilitating access to medicines by, for instance, incorporating a model of human rights into its national patent law through the adoption of flexibilities such as compulsory licensing, pharmaceutical companies equally have a baseline responsibility to respect and comply with such national laws (in accordance with Guidelines 3, 26 and 27). It is not the responsibility of pharmaceutical companies to enact laws or adopt public policies geared towards improving access to medicines. However, where a state has taken decisive action in this regard, it is difficult to understand why a

¹⁰⁵ Ibid 23-24.

¹⁰⁶ Moon, note 5, 40.

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

demand that pharmaceutical companies should ‘consider all the arrangements at its disposal with a view to ensuring that its medicines are affordable to as many people as possible’ (as specified in Guideline 33) falls far beyond the baseline responsibility of pharmaceutical companies to respect the right to health. Moon’s criticisms in this regard is only applicable to a country that has failed, for reasons best known to it, to take decisive action to facilitate access to medicines.

Furthermore, there are instances where it might be in the best interests of a pharmaceutical company to actually take steps to ensure that its patented pharmaceutical products are sold at a reasonably affordable price. One of the grounds upon which a compulsory licence was granted with respect to Bayer’s drug, Nexavar, was Bayer’s failure to sell the patented drug at a price that was reasonably affordable as required by section 84(1)(b) of the Indian Patents Act. In actual fact, in that case, the Indian Controller of Patents questioned why Bayer had not engaged in differential pricing (one of the arrangements suggested in Guideline 33) with respect to the sale of its patented drug in India.¹⁰⁹

It is noteworthy that, apart from granting voluntary licences to seven generic drug companies in India, Gilead Sciences also announced in 2014 that it would be launching its Hepatitis C drug, Solvadi, in India at a price of \$900 for a 12-week course.¹¹⁰ It bears noting that Solvadi

¹⁰⁹ *Natco v Bayer*, Compulsory License Application No. 1 of 2011, (Decision of the Indian Controller of Patents, 9 March 2012) para 11. The Controller stated that, ‘[The] Patentee also submitted that affordable to [the] public is required to be considered as affordable to different classes/sections of [the] public. On this point, I fully agree with the Patentee. I only wonder why the Patentee did not execute this concept by offering differential pricing for different classes/sections of [the] public in India.’

¹¹⁰ Rupali Mukherjee, ‘New Hepatitis-C Drug 99% Cheaper in India,’ *The Times of India*, (6 August 2014), <http://timesofindia.indiatimes.com/india/New-Hepatitis-C-drug-99-cheaper-in-India/articleshow/39719323.cms> (accessed 12 March 2017).

is being sold in the US at the cost of \$84,000 for a 12-week course.¹¹¹ In addition, apart from promising to take steps to issue voluntary licences with respect to its own Hepatitis C drug, daclatasvir, BMS equally announced in 2014 that it will utilize tiered pricing with regard to the drug.¹¹² According to BMS, its ‘tiered pricing model for daclatasvir will take into consideration several factors, including countries’ economic development and burden of disease, as well as the commitment of the government to holistically address hepatitis C, including treatment and care’ and that ‘[t]he lowest pricing tier will apply to all low-income and least developed countries’.¹¹³

However, it is unclear whether the actions of both Gilead Sciences and BMS with regard to taking steps to facilitate greater access to their Hepatitis C drugs was motivated by a desire to comply with either Ruggie’s Guiding Principles or the Hunt Guidelines. It is possible that both companies were simply motivated by the desire to voluntarily engage in what they might perceive as socially desirable activities and not necessarily as compliance with any corporate responsibility to respect the right to health.¹¹⁴

¹¹¹ Eric Palmer, ‘Gilead Sciences Prices Sovaldi in India at a Tiny Fraction of U.S. Cost,’ *FiercePharma*, (7 August 2014), <http://www.fiercepharma.com/story/gilead-sciences-prices-sovaldi-india-tiny-fraction-us-cost/2014-08-07> (accessed 12 March 2017).

¹¹² Helfand, note 93.

¹¹³ *Ibid.*

¹¹⁴ Gilead (2014), note 89, (stating that the voluntary licence agreements entered into with the Indian generic drug companies ‘are essential to advancing the goals of [Gilead’s] humanitarian program in these countries’ and that Gilead makes it a priority to increase access to its medicines for people who can benefit from them, regardless of where they live or their economic means.’). See also, Helfand, note 93, (stating that as part of Bristol-Myers Squibb’s ‘Company-wide commitment to increasing access to medicines for patient populations in need, [it has] initiated discussions with government health authorities and other stakeholders in a number of developing countries to facilitate access to daclatasvir.’).

Nevertheless, the actions of both Gilead Sciences and BMS in this regard can equally be construed as a means of preventing the grant of compulsory licences (in countries such as India) on their patented drugs.¹¹⁵ In other words, by taking steps to facilitate greater access to their Hepatitis C drugs, it can be argued that these companies are seeking to comply with the provisions of national patent laws (such as section 84(1)(b) of the Indian Patents Act) which demand (with the threat of the grant of a compulsory licence where a patentee fails to comply) that patented products should be sold at prices that are reasonably affordable. Thus, by seeking to comply with such provisions contained in the national patent laws, these companies can be said to be acting in accordance with Guideline 3 and also discharging their baseline responsibility to respect the right to health as specified in the Guiding Principles.

¹¹⁵ Palmer, note 111, (noting that, ‘Drugmakers have other considerations to factor in when pricing essential but expensive drugs in India. The government has, and has exercised, the authority to grant a compulsory license for a drug that it considers essential but too expensive for the Indian market, where few people have insurance. When that happens the drugmaker not only loses direct sales in India but also runs the risk of losing control of its product.’). See also, Rupali Samuel, ‘Access to Medicines for Hepatitis C: Part II – Evaluating the Arsenal,’ *Spicy IP*, (19 August 2014), <http://spicyip.com/2014/08/access-to-medicines-for-hepatitis-c-evaluating-the-arsenal-part-ii.html> (accessed 12 March 2017), (noting that, ‘Given the extremely high incidence of 12 million patients with [Hepatitis C] in India alone, the threat of a compulsory licence (CL) was acute in the event that Gilead did not modify [the price of Solvadi in India].’). See further, Rupali Samuel, ‘Gilead Enters into Licences with 7 Indian Generics for Manufacture and Sale of Sovaldi,’ *Spicy IP*, (17 September 2014), <http://spicyip.com/2014/09/gilead-enters-into-licenses-with-7-indian-generics-for-manufacture-and-sale-of-sovaldi.html> (accessed 12 March 2017), (noting that, ‘What is certain for India is that these [voluntary licences granted by Gilead] are likely to render the grant of [a] compulsory license on the drug ... highly improbable since the grounds of reasonable access, affordable price and working of the patent [as specified in section 84(1) of the Indian Patents Act] are likely to be unavailable.’).

CONCLUSION

The overlap in the mandates of the former Special Rapporteur on the right to health (Paul Hunt) and the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises (John Ruggie) has resulted in some inconsistencies between the Guidelines developed by Hunt and the Guiding Principles developed by Ruggie as it relates to the right to health responsibilities of pharmaceutical companies. Nevertheless, it is still possible to delineate the scope of the right to health responsibilities of pharmaceutical companies through an interpretation of the Hunt Guidelines in the light of the Guiding Principles.

Based on the analysis in this article, it can be concluded that, in relation to facilitating access to affordable medicines, both states and pharmaceutical companies have specific roles to play. States must take seriously their primary responsibility of respecting, protecting, and fulfilling the right to health by incorporating a model of human rights into their national patent laws. Furthermore, pharmaceutical companies must take seriously their baseline responsibility to respect the right to health and comply with the provisions contained in national patent laws that are designed to facilitate access to medicines.